Remarks

The undersigned would like to thank the Examiner for the interview on September 20, 2006 regarding the amendment and response after final filed on August 21, 2006. In the interview, the Examiner indicated that the amendment filed on August 21, 2006 would be entered provided that the proposed amendments to claims 15 and 22 were withdrawn. The proposed amendments to claims 15 and 22 have been deleted as the Examiner requested. Entrance of the amendment is respectfully requested.

Claim 1 has been amended to specify that the composition contains a therapeutically effective amount of at least one herbal active agent. Support for the amendment is found, for example, on page 9, lines 1-5. Claim 1 has also been amended to delete the term "homeopathic agents", to delete the reference to drugs and the subsequent Markush group, and to correct the punctuation.

Claim 6 has been amended to delete the term "homeopathic agents".

Claim 22 has been amended to correct a typographical error.

Claim 23 has been amended to insert the word "the" before the word "polymer" in line 1 of the claim.

No new matter is added by these amendments and should be entered on the basis that they remove issues on appeal, as discussed below.

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 1-4, 6-12, 14-17, 19-26, and 38 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The Examiner alleges that claim 1 is not enabled for a solid, self-bioadhesive composition comprising a therapeutically effective amount of a homeopathic agent. Specifically, the Examiner alleges that at the time the application was filed, the state of the art did not fully support the incorporation of homeopathic agents or homeopathic amounts of active agents into pharmaceutical compositions intended for administration to patients. Without making any admissions, and solely for the purpose of facilitating prosecution, claims 1 and 6 have been amended to delete the term "homeopathic agent". Accordingly, claim 1, as amended, and the claims dependent thereon, are enabled.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 15-17 and 19-21 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Specifically, the Examiner alleges that the phrase "further comprising a non-herbal active agent" is indefinite since claim 1 defines the active agent as an herbal agent, a homeopathic agent, or a drug. Without making admissions, and solely for the purpose of facilitating prosecution, claim 1 has been amended to delete the reference to drug and the subsequent Markush group.

Rejection Under 35 U.S.C. § 102

Claims 1-4, 6, 15-17, 22-24, 26, 27, and 38 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,772,470 to Inoue *et al.* ("Inoue"). Applicants respectfully traverse this rejection. Claims 1-3, 15-17, 22-24, 26, 27, and 38 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,226,848 to Nagai *et al.* ("Nagai"). Applicants respectfully traverse this rejection as applied to the

claims as amended. Note there appears to be an error in the Examiner's rejection as claim 27 was previously canceled and therefore is not pending.

a. U.S. Patent No. 4,772,470 to Inoue et al. ("Inoue")

Inoue describes an oral bandage comprising a soft adhesive film comprising a mixture of polycarboxylic acid and/or a polycarboxylic acid anhydride and a vinyl acetate polymer and having incorporated therein a topical drug (abstract). Inoue does not disclose a composition comprising a bioadhesive carrier in an amount from about 40 to 99 percent based *on the weight of the whole composition* as required by claim 1.

Inoue discloses that the *dissolution ratio* of the polycarboxylic acid is 40% by weight or less. Dissolution ratio is not the same as weight percent of the total composition. The dissolution ratio is the ratio of polycarobxylic acid that dissolved in water from a polycarboxylic acid-polyvinyl acetate film divided by the amount of the polycarboxylic acid contained in the film (col. 4, lines 35-44). The dissolution ratio does not take into account the amount of active agent, excipients, and or support films present in the composition. The dissolution rate provides information regarding compatibility of the polycarboxylic acid and the polyvinyl acetate, not weight percent of the final composition. In the examples, the polycarboxylic acid-polyvinyl acetate is laminated to a support film. No information is given regarding the weight of the support film, thus the weight percent of the bioadhesive material cannot be determined. Inoue does not disclose each and every element of claim 1.

Inoue also does not disclose the compositions specified in claims 2 and 3. Inoue discloses films, not compressed tablets. Accordingly, claim 1, and the claims dependent thereon, are novel over Inoue.

b. U.S. Patent No. 4,226,848 to Nagai et al. ("Nagai")

Nagai describes pharmaceutical preparations comprising a water-swellable and mucosa-adhesive polymeric matrix comprising about 50% to about 95% by weight of a cellulose ether and about 50 to about 5% by weight of a homo or copolymer of acrylic acid and dispersed therein a pharmaceutically effective amount of medicament (abstract). Suitable medicaments are listed on at col. 5, line 58 to col. 6, line 17. Nagai does not disclose a composition comprising at least one herbal active agent as required by claim 1, as amended. The bioadhesive carrier in the claimed compositions does not require the presence of cellulose ethers as disclosed in Nagai. Accordingly, the claims, as amended, are novel over Nagai.

Rejection Under 35 U.S.C. § 103

Claims 1-4, 6-12, 15-17, 19, 22-27, and 38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Inoue, in view of U.S. Patent No. 5,939,050 to Iyer *et al.* ("Iyer") and U.S. Patent No. 6,197,305 to Friedman *et al.* ("Friedman") with evidence provided by Lawless, The Illustrated Encyclopedia of Essential Oils ("Lawless"). Applicants respectfully traverse this rejection.

a. Inoue

As discussed above, Inoue does not disclose a composition comprising a bioadhesive carrier in an amount from about 40 to 99 percent based *on the weight of the whole composition* as required by claim 1.

b. U.S. Patent No. 5,939,050 to Iyer et al. ("Iyer")

Iyer describes antimicrobial compositions comprising at least two antimicrobial agents which exhibit reduced MIC values relative to the MIC values for the agents

making up the combination when measured alone (abstract). Iyer does not disclose a solid, self-bioadhesive tablet formulation for topical application that adheres to the oral mucosal tissue. As noted at col. 7, lines 16-27 and lines 53-61, these formulations are oral rinses, mouth washes or cleansers.

c. U.S. Patent No. 6,197,305 to Friedman et al. ("Friedman")

Friedman describes an anti-fungal composition containing (a) an extract of botanical materials, the botanical materials including material from Echinacea species and Propolis; and (b) an essential oil (abstract). The composition can be in the form of a mouthwash, a suppository, or a cream. Friedman does not disclose a solid, self-bioadhesive composition for topical application that adheres to the oral mucosal tissue. The formulations are not bioadhesive. Ingredients such as those at col. 7 are either hydrophobic (such as beeswax) or liquid (glycerin and oil) or contain detergent (such as sodium lauryl sulfate). Table 3 describes a liquid mouthwash formulation, not a solid. Table 4 described an oral gel primarily of polyethylene glycol, which is not bioadhesive alone. Tables 5 and 6 described hydrophobic skin cream.

d. Lawless, The Illustrated Encyclopedia of Essential Oils ("Lawless")

Lawless describes that the essential oil of lemon contains approximately 70% limonene as well as sabinene, myrcene, and pinenes (page 120). Lawless does not disclose a self-bioadhesive composition for topical application that adheres to oral mucosal tissue, nor a homeopathic amount.

e. The references alone, or in combination, do not disclose each and every element of the claims

In order to establish a *prima facie* case of obviousness, the references, alone or in combination, must disclose each and every element of the claims (*In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974) "[t]o establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.."). As discussed above, Inoue does not disclose a composition comprising a bioadhesive carrier in an amount from about 40 to 99 percent based *on the weight of the whole composition* as required by claim 1. The remaining references do not disclose or suggest the elements missing from Inoue. Further, none of the references disclose or suggest a composition in the form of a compressed tablet as specified in claims 2 and 3. Therefore, the claims are not obvious over Inoue in view of Iyer and Friedman with evidence by Lawless.

f. One of ordinary skill in the art would not be motivated to combine the references to arrive at the claimed compositions

As discussed above, Inoue does not disclose a composition comprising a bioadhesive carrier in an amount from about 40 to 99 percent based *on the weight of the whole composition* as required by claim 1. None of the remaining references discloses solid bioadhesive compositions. One of ordinary skill in the art would not be motivated to modify and/or combine Inoue with Iyer, Friedman, and Lawless to arrive at the claimed compositions. Even if one were motivated to combine the references, one would prepare compositions containing a bioadhesive carrier wherein the dissolution ratio of the polycarboxylic acid was less than 40%; not a composition wherein the carrier is present in an amount from about 40 to 99 percent based *on the weight of the whole composition*

as required by claim 1. Accordingly, the claims are not obvious over Inoue in view of Iyer and Friedman with evidence by Lawless.

Claim Objections

Claim 15 was objected to under 37 C.F.R. § 1.75(c) as being in improper dependent form for failing to further limit the subject matter of a previous claim. Without making any admission, and solely for the purpose of facilitating prosecution, claim 15 has been canceled.

Allowance of claims 1-4, 6-12, 14-17, 19-26, and 38, as amended, is respectfully solicited.

Respectfully submitted,

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